

§ 884.6130 Assisted reproduction microtools.

(a) *Identification.* Assisted reproduction microtools are pipettes or other devices used in the laboratory to denude, micromanipulate, hold, or transfer human gametes or embryos for assisted hatching, intracytoplasmic sperm injection (ICSI), or other assisted reproduction methods.

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing).

§ 884.6140 Assisted reproduction micropipette fabrication instruments.

(a) *Identification.* Assisted reproduction micropipette fabrication devices are instruments intended to pull, bevel, or forge a micropipette or needle for intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) or other similar assisted reproduction procedures.

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing).

§ 884.6150 Assisted reproduction micromanipulators and microinjectors.

(a) *Identification.* Assisted reproduction micromanipulators are devices intended to control the position of an assisted reproduction microtool. Assisted reproduction microinjectors are any device intended to control aspiration or expulsion of the contents of an assisted reproduction microtool.

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing).

§ 884.6160 Assisted reproduction labware.

(a) *Identification.* Assisted reproduction labware consists of laboratory equipment or supplies intended to prepare, store, manipulate, or transfer human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures. These include syringes, IVF tissue culture dishes, IVF tissue culture plates, pipette tips, dishes, plates, and other

vessels that come into physical contact with gametes, embryos or tissue culture media.

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing).

§ 884.6170 Assisted reproduction water and water purification systems.

(a) *Identification.* Assisted reproduction water purification systems are devices specifically intended to generate high quality, sterile, pyrogen-free water for reconstitution of media used for aspiration, incubation, transfer or storage of gametes or embryos for in vitro fertilization (IVF) or other assisted reproduction procedures. These devices may also be intended as the final rinse for labware or other assisted reproduction devices that will contact the gametes or embryos. These devices also include bottled water ready for reconstitution available from a vendor that is specifically intended for reconstitution of media used for aspiration, incubation, transfer, or storage of gametes or embryos for IVF or other assisted reproduction procedures.

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, water quality testing, design specifications, labeling requirements, biocompatibility testing, and clinical testing).

§ 884.6180 Reproductive media and supplements.

(a) *Identification.* Reproductive media and supplement are products that are used for assisted reproduction procedures. Media include liquid and powder versions of various substances that come in direct physical contact with human gametes or embryos (including water, acid solutions used to treat gametes or embryos, rinsing solutions, sperm separation media, supplements, or oil used to cover the media) for the purposes of preparation, maintenance, transfer or storage. Supplements are specific reagents added to media to enhance specific properties of the media (e.g., proteins, sera, antibiotics, etc.).

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing).

§ 884.6190 Assisted reproductive microscopes and microscope accessories.

(a) *Identification.* Assisted reproduction microscopes and microscope accessories (excluding microscope stage warmers, which are classified under assisted reproduction accessories) are optical instruments used to enlarge images of gametes or embryos. Variations of microscopes and accessories used for these purposes would include phase contrast microscopes, dissecting microscopes and inverted stage microscopes.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[63 FR 48436, Sept. 10, 1998, as amended at 64 FR 62977, Nov. 18, 1999; 66 FR 38809, July 25, 2001]

§ 884.6200 Assisted reproduction laser system.

(a) *Identification.* The assisted reproduction laser system is a device that images, targets, and controls the power and pulse duration of a laser beam used to ablate a small tangential hole in, or to thin, the zona pellucida of an embryo for assisted hatching or other assisted reproduction procedures.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems." See § 884.1(e) for the availability of this guidance document.

[69 FR 77624, Dec. 28, 2004]

PART 886—OPHTHALMIC DEVICES

Subpart A—General Provisions

Sec.

886.1 Scope.

886.3 Effective dates of requirement for premarket approval.

886.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

886.1040 Ocular esthesiometer.
 886.1050 Adaptometer (biophotometer).
 886.1070 Anomaloscope.
 886.1090 Haidinger brush.
 886.1120 Ophthalmic camera.
 886.1140 Ophthalmic chair.
 886.1150 Visual acuity chart.
 886.1160 Color vision plate illuminator.
 886.1170 Color vision tester.
 886.1190 Distometer.
 886.1200 Optokinetic drum.
 886.1220 Corneal electrode.
 886.1250 Euthyscope.
 886.1270 Exophthalmometer.
 886.1290 Fixation device.
 886.1300 Afterimage flasher.
 886.1320 Fornixscope.
 886.1330 Amsler grid.
 886.1340 Haploscope.
 886.1350 Keratoscope.
 886.1360 Visual field laser instrument.
 886.1375 Bagolini lens.
 886.1380 Diagnostic condensing lens.
 886.1385 Polymethylmethacrylate (PMMA) diagnostic contact lens.
 886.1390 Flexible diagnostic Fresnel lens.
 886.1395 Diagnostic Hruby fundus lens.
 886.1400 Maddox lens.
 886.1405 Ophthalmic trial lens set.
 886.1410 Ophthalmic trial lens clip.
 886.1415 Ophthalmic trial lens frame.
 886.1420 Ophthalmic lens gauge.
 886.1425 Lens measuring instrument.
 886.1430 Ophthalmic contact lens radius measuring device.
 886.1435 Maxwell spot.
 886.1450 Corneal radius measuring device.
 886.1460 Stereopsis measuring instrument.
 886.1500 Headband mirror.
 886.1510 Eye movement monitor.
 886.1570 Ophthalmoscope.
 886.1605 Perimeter.
 886.1630 AC-powered photostimulator.
 886.1640 Ophthalmic preamplifier.
 886.1650 Ophthalmic bar prism.
 886.1655 Ophthalmic Fresnel prism.
 886.1660 Gonioscopic prism.
 886.1665 Ophthalmic rotary prism.
 886.1670 Ophthalmic isotope uptake probe.
 886.1680 Ophthalmic projector.
 886.1690 Pupillograph.
 886.1700 Pupillometer.
 886.1750 Skiascopic rack.
 886.1760 Ophthalmic refractometer.
 886.1770 Manual refractor.
 886.1780 Retinoscope.
 886.1790 Nearpoint ruler.
 886.1800 Schirmer strip.
 886.1810 Tangent screen (campimeter).
 886.1840 Simultan (including crossed cylinder).